8EHQ-1003-15446

degussa.

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October 6, 2003

Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Contain NO CBI

Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

270302

These studies were made available to Degussa Corporation in April 2003. Degussa's toxicologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,

Shaun F. Clancy, Ph.D.

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404

Degussa Corporation

Memo

To: File

From: Shaun Clancy

CC:

Date: 10/06/03

Re: TSCA 8(e) Review – 2516-33-8

Two endpoints were provided by Fine Chemicals for 2516-33-8 Cyclopropyl carbinol

- Acute Oral Tox
- Skin Irritation

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk is minimal.

There were signs of neurotoxicity and there were target organ effects observed to a number of abdominal organs. Given the high dose, other toxic effects and the reversibility of the possible neurotoxic effects, it is not clear that the potential neurotoxic effects are actually due to neurotoxicity. It is concluded that these effects may be considered to be reportable under TSCA 8(e) and will be submitted.

Contains **No CBI**

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Fine chemicals
Chemicals Safety
Management

FC-TME-CSM/Dr.Jbi/sch

August, 6 2003

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 11

cc: Dr. W. Mayr/FC-TME-CSM

Initial notice of Information for possible TSCA 8e submission
Cyclopropyl carbinol, CAS No. 2516-33-8

Dear Shaun,

Please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability.

I am at your disposal for any further questions.

English translations of the summaries and/or results of the studies are attached.

Best regards

Sylvia Jacobi

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Fine chemicals
Chemicals Safety
Management

August 6, 2003

Initial Notice of Information to be assessed for Possible TSCA, Sec. 8e Reporting

Name / Trade name of the Substance	**Cycloprpylcarbinol/Cyclopropanemethanol**
CAS-No.:	2516-33-8

Human Health Effects [X]

Environmental Effects [ ]

Degussa-Study-No.:	87-0290-DKT 87-0292-DKT
Other Source of information:	

Summary of Adverse Effects
Acute oral toxicity study in rats
Source Degussa AG, unpublished report No. 85-0290-DKT
Guideline OECD 401, non-GLP

Doses of 501, 631, 794, and 1000 mg/kg bw were administered undiluted (Volume 0.551 to 0.873 ml/kg bw) to groups of 5 male and 5 female Wistar rats.

The LD50 was 631 mg/kg bw.. Clinical symptoms appeared 30 to 60 min after adminsitration of the test substance. Symptoms included staggered gait, slowing of movements, squatting position (some animals), slight sedation, ataxia, stenous respiration. Later abdominal position, slight to severe sedation, ataxia, hypothermia, diarrhoea, loss of body weight, dark, small, bloody eyes, pallor of extremities, hunched posture, twitching, blood in urine and faeces. The symptoms resolved after 7 to 12 days.

Hyperemia of the gastric, intestinal and peritoneal mucosa, thickening of the forestomach mucosa, discoloration of liver, kidneys and spleen, invaginations of the small intesitne and colon, liver cirrhosis were observed in animals that died during the study. Animals that were sacrificed at the end of the observation period showed in one animal thickening of the forestomach mucosa and in another one purulent foci in kidney and liver.

Acute skin irritation study in rabbits
Source: Degussa AG, unpublished report No. 85-0292-DKT
Guideline: OECD No. 404 (1981), non-GLP.

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0.5 ml of the test substance was applied to the shaved back Six rabbits (3m, 3f) for 4 h under occlusive conditions. Erythema grade 4 and Edema grade 2.78 was observed (mean of 6 animals after 24, 48, 72 h). Necrosis was observed from 1 h after removal of the patch and did not resolve within 72 h. Scab and eschar formation was observed from day 6 to day 14. Two animals showed scar formation on day 14. After an exposure time of 3 minutes necrosis did not occur. The substance was shown to be corrosive to rabbit skin in this test system.

Nature and Extent of Risk Involved:
Risk of incapapcitation due to severe irrtation and corrosion to skin and possivbly eyes.
Possible neurotoxic effects and secondary effects due to corrosivity after oral ingestion.

Information by	Date:
Dr. Sylvia Jacobi	August 6, 2003

Hüls AG
PS Biology/Toxicology

Copy No. 3

Marl, 9/24/1987

Report No. 1035

Acute Oral Toxicity of Cyclopropyl carbinol in Rats

by

P. Mürmann

Degussa-Hüls AG – REG No.
87 0290 DKT

Summary

An acute oral toxicity determination in male and female rats revealed that the LD_{50} value of cyclopropyl carbinol is 631 mg/kg body weight. The treated animals were free of intoxication symptoms within maximum 12 days. The body weight gain was temporarily delayed. The dissections at the end of the study showed partial thickening of the forestomach mucosa in one animal and purulent foci on the kidneys and liver of one animal.

V The results of the experiment are shown in the following table.

Cyclopropyl carbinol
Acute oral toxicity (LD_{50}) for rats

Dose (mg/kg)	Sex	Toxicological Result	Number of Hours Within Which Death Occurred	LD_{50} (mg/kg)
501	male	0/5/5*		
	female	3/5/5	132	
				631 (505-789)
631	male	1/5/5		Gradient function
	female	4/5/5	72	S – 1.56
794	male	2/5/5		
	female	5/5/5	75	

*Number of animals that died / number of animals with symptoms / number of animals used.

Body Weight Trend (mean values) in g

Dose (mg/kg)	Before Administration (fasting)	24 Hr. After Administration	1 Wk. After Administration	2 Wks. After Administration	Weight Gain
501	127.2	117.4	152.1	180.7	53.5
631	123.6	116.0	144.6	180.6	57.0
794	149.9	134.4	160.7	197.3	47.4

The treatment had a transient inhibitory effect on the development of the body weights. Starting 30-60 min after administration, the animals exhibited ruffled fur, staggering, slowed motion; squatting position in some cases; slight sedation, ataxia and respiratory difficulties (audible breathing). Later, the animals additionally exhibited abdominal position at times and mild to severe sedation and ataxia, hypothermia, slowed respiration, diarrhea, weight loss, half-closed eyes, dark, small, bloodshot eyes, pale extremities, vocalizations when touched, hunched posture, twitching, bloody urine and bloody feces, prolapsed penis and fouled anal region. After 7-12 days, the animals were free of

symptoms of intoxication. The post-mortem dissections revealed hyperemia (some severe) of the intestinal and gastric mucosae, and in some cases, of the peritoneum, thickening of the forestomach mucosae, discoloration of the liver, kidneys and spleen, intestinal invaginations (large and small intestine) and cirrhosis-like changes of the livers. The dissections at the end of the study showed a partial thickening of the forestomach mucosa in one animal and pus foci on the left kidney and liver in one animal.

Author and Study Director

[Signature]
(Dr. P. Mürmann)
Veterinary Specialist in Pharmacology and Toxicology

Hüls AG
WL Product Safety
- Toxicology -

Copy No. 3

Marl, Sept. 3, 1987

Report No. 1036

Testing the Acute Skin Irritant Action of

Cyclopropyl carbinol

by

P. Mürmann

Degussa-Hüls AG – REG No.
87 – 0292 - DKT

I Summary:

Cyclopropyl carbinol

was tested on the shorn dorsal skin of rabbits to test its acute skin irritant action. The product was applied undiluted and the exposure time in the patch test was 4 hr.

Results:

The cyclopropyl carbinol produced necrosis on the skin of male and female rabbits and hence shows a caustic irritant action (irritation index: 7/8).
After an exposure time of only 1 hr, necrosis was observed, but not after an exposure time of 3 min.

V **Results:**

The test results are contained in the following table.

Numerical evaluation of the reactions, individual values and mean values.

Animal No.	Ear No.	Sex	1 Hr		24 Hr		48 Hr		72 Hr		6 Days		8 Days		10 Days		14 Days	
			R	S	R	S	R	S	R	S	R	S	R	S	R	S	R	S
1	34177	M	N4	4	N4	4	N4	4	N4	4	NV4	4	NV4	4	rb K		rb K	
2	34183	M	x4	4	x4	3	x4	2	x4	2	xVSc4	2	xVSc4	2	x Sc K		x K	iA
3	34209	M	x4	3	x4	3	x4	3	x4	2	xVSc4	2	x Sc		x Sc		xSc	iA
4	33172	F	x4	4	x4	2	x4	2	x4	2	rb Scp		rb Scp		rb Scp		Na	
5	33230	F	x4	3	x4	3	x4	1	x4	1	Sc		Sc		Sc		SciANa	
6	33306	F	*N4	4	NV4	4	NV4	4	NV4	4	NV 4	4	NV 4	4	NV4	4	rb K	

$\bar{x}$ absolute 7.67 7.17 6.67 6.50

↓

28.01: 4 = 7.00 = irritation index

R = reddening
S = swelling
* = necrosis on removal of patch
x = necrotic spots on the application area (1-2 cm)
N = necrosis
V = hardening
Sc = scab
rb = red-brown
Scp = scab plate
iA = detaching
K = crust
Na = scar

Thus, the irritation index was 7/8 + necrosis, indicating that single dermal application of 0.5 cc of cyclopropylcarbinol has a caustic action on male and female rabbits. After 1 hr of exposure, there was also necrosis, but not after 3 minutes.

Evaluation according to Appendix VI of the Council Directive 79/831/EEC amending 67/548/EEC for the sixth time:

reddening: $\bar{x} = 4.00$

edema: $\bar{x} = 2.78$

Author and Study Director

[Signature]
(Dr. P. Mürmann)
Veterinary Specialist in Pharmacology and Toxicology